DGMC – Human Research
Final Report

1. DATE: 5 May 2014

2. Protocol Number: FDG20100017H

3. Title: Incidence of Venous Thromboembolism (VTE) and Effect of Thrombosis Prophylaxis Guidelines in Patients Transported Aeromedically

4. Risk: ☐ **Greater than Minimal Risk** **X Minimal Risk**

5. Date of Approval: 18 May 2010

6. Start Date: 15 Nov 2010

7. Study Staff

Name	Rank	Study Role	Date of Investigator Training	Staff/ Resident/ Fellow/ Civilian	Dept/ Office Symbol	Phone	E-mail
Kohler, Maria	Maj	PI	17 Oct 2011	Staff	SGHI	423-3713	maria.kohler@us.af.mil
Hatzfeld, Jennifer	LtCol	AI	2 Mar 2011	Staff	USAMRMC	301-619-0236	jennifer.j.hatzfeld.mil@mail.mil
Dukes, Susan	Lt Col	AI	5 Dec 2011	Staff	USAFSAM / FHC	937-656-8482	susan.dukes@wpafb.af.mil

8. Study Status:
(Check one only)
☐ Inactive, protocol never initiated
X Inactive, protocol initiated but has not/will not be completed
☐ All approved procedures/uses have been completed

9. Number of Subjects Entered into the Study: For multiple sites, add rows to the table below for each site.

	Number approved to enroll	**Number enrolled**	**Withdrawals**
Number of subjects enrolled at DGMC	N/A	N/A	N/A
Number of subjects enrolled at _____	N/A	N/A	N/A
Data from patients transported aeromedically	Approx. 40,000	65,536	N/A

Report Documentation Page

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
05 MAY 2014	**Final**	**18 May 2010 - 05 May 2014**

4. TITLE AND SUBTITLE
FDG20100017H Incidence of venous thomboembolism 9VTE) and effect of thrombosis prophylaxis guidelines in patients transported aeromedically.

5a. CONTRACT NUMBER

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Lt Col Jennifer Hatzfeld, Maj Maria Kohler, Lt Col Susan Dukes

5d. PROJECT NUMBER
FDG20100017H

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Clinical Investigation Facility David Grant Medical Center 101 Bodin Circle Travis AFB, CA 94535

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
Clinical Investigation Facility David Grant Medical Center 101 Bodin Circle Travis AFB, CA 94535

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release, distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
Initial data on patients with existing VTE was received from USTRANSCOM in 2010, but did not include data on the other patients. This was addressed by granting the PI permission to use TRAC2ES. Eventually, the TRAC2ES data was received via secure website. With an approved TMA DSA in place (approved 23 Jan 2013), the M2 data was extracted and compiled by the Knowledge Center. In the process, it was learned that the M2 data prior to year 2007 was not accessible and the TRACES data only included years 2002- 2009. All data was stored on an approved external drive. The two data sets (M2 and TRACES) for the years 2007, 2008 and 2009 were merged successfully. Merger was done with SSN, FMP, and DOB. Based on the analysis, the main finding is that the U.S. military personnel (including active duty, guard and reserve members) age 25-31 that were transported aeromedically during 2007-2009 were at higher risk for developing a VTE than members age 18-21, keeping rank and sex constant. In conclusion, this study did not meet the proposed objectives. The analysis of the merged data revealed duplicate records (mostly in M2 data set) or missing information (mostly in TRACES data base). This posed difficulty in performing an efficacious analysis and providing answers to study questions.

15. SUBJECT TERMS
U.S. Air Force, Medical Service, Medical Research, Graduate Medical Education

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			
unclassified	**unclassified**	**unclassified**	**SAR**	**4**	

Data from patients admitted to MTFs	Approx. 500,000	Approx. 600,000	N/A

9.1. Summary of Unanticipated Problems and Adverse Events:

The study had Unanticipated Problems:
☐ Yes X No
The study had Adverse Events:
☐ Yes X No
All adverse, serious adverse and unexpected events were reported IAW SGSE 40-402-01:
☐ Yes ☐ No X N/A

List all the local and sponsor reported unanticipated problems, serious and non-serious adverse events, reported to the sponsor and protocol deviations that resulted in subject harm since the last progress report.

If none occurred, state NONE.

Type of Event*	Date of Event	Date Reported	Description of Event	Site of Event (for multisite)	Outcome
NONE					

*Unexpected adverse event, severe adverse event, or adverse event

Reminder if these events were study related, caused harm or increased the risks to subjects or others, they should have already been reported when discovered, using the Adverse or Unexpected Adverse Event report form. This is only a summary of those events.

9.2. Summary of Withdrawals from the Study: If none occurred, state NONE. List all subjects who withdrew (please specify if the subject withdrew, is lost to follow-up, deceased or any other reasons from your study)

For the Entire Study Chronologically

Date of Withdrawal	Subject Number	Reason for Withdrawal
NONE		

9.3. Consent Process: N/A (a waiver of informed consent was granted by the IRB)

10. Study Deviations

Have any minor non-compliance events occurred? ☐ Yes X No
Have any serious non-compliance events occurred? ☐ Yes X No

List any instances of non-compliance minor or serious

NONE

I certify that no changes have occurred in the protocol since the previous IRB review. X Yes ☐ No

11. Complaints about the Study:
Have there been any reported complaints regarding the study?
☐ Yes X No

List all complaints about your study, for the Entire study. **If no complaints occurred, state NONE and delete the table below. Do not use N/A**

For the Entire Study Chronologically

Date of Complaint	Reason for Complaint
NONE	

12. Amendments:
List all amendments/changes made to the protocol, Informed Consent or investigator's brochure. **IF none occurred, state NONE. Do not use N/A.**

For the Entire Study Chronologically

Date of Change	Date of Approval	Summary of the Change
6 Jan 2012	18 Jan 2012	Addition of Maj Sue Dukes as an AI.
20 Jan 2012	21 Feb 2012	Change in PI from Maj Jennifer Hatzfeld to Maj Maria Kohler due to deployment.

13. Funding: N/A; there was no funding requested/obtained to complete this research protocol.

14. Summary of Research Findings:

Initial data on patients with existing VTE was received from USTRANSCOM in 2010, but did not include data on the other patients. This was addressed by granting the PI permission to use TRAC2ES. Eventually, the TRAC2ES data was received via secure website. With an approved TMA DSA in place (approved 23 Jan 2013), the M2 data was extracted and compiled by the Knowledge Center. In the process, it was learned that the M2 data prior to year 2007 was not accessible and the TRACES data only included years 2002- 2009. All data was stored on an approved external drive.

The two data sets (M2 and TRACES) for the years 2007, 2008 and 2009 were merged successfully. Merger was done with SSN, FMP, and DOB.

Data analysis (using STATA statistical software):

```
------------------------------------------------
    fy   |  sum(num)  sum(denom)
---------+--------------------------------------
  2007 |       85        2833
  2008 |       46        2104
  2009 |       61        2027
------------------------------------------------
. poisson num a2-a4 r2-r4 sex, exposure(denom) irr

Iteration 0:  log likelihood = -94.857155
Iteration 1:  log likelihood = -94.792536
Iteration 2:  log likelihood =  -94.79247
Iteration 3:  log likelihood =  -94.79247
```

Poisson regression — Number of obs = 81
LR chi2(7) = 22.10
Prob > chi2 = 0.0024
Log likelihood = -94.79247 — Pseudo R2 = 0.1044

num	IRR	Std. Err.	z	P>|z|	[95% Conf.	Interval]
age 22-24	1.294108	.3389849	0.98	0.325	.7744668	2.162412
age 25-31	1.889428	.480855	2.50	0.012	1.147365	3.111424
age 32+	1.678688	.4585076	1.90	0.058	.9828283	2.86723
rank E5-E9	1.287155	.2302374	1.41	0.158	.9065128	1.827629
rank O1-O3	1.561388	.4690277	1.48	0.138	.8665972	2.813226
rank O4-O6	.7306002	.3902467	-0.59	0.557	.2564569	2.08135
sex	1.496067	.4158372	1.45	0.147	.867674	2.57956
_cons	.0112987	.0036968	-13.70	0.000	.0059501	.0214552
ln(denom)	1 (exposure)					

Key:
Age comparison group = age 18-21
Rank comparison group = rank E1-E4

Based on the analysis, the main finding is that the U.S. military personnel (including active duty, guard and reserve members) age 25-31 that were transported aeromedically during 2007-2009 were at higher risk for developing a VTE than members age 18-21, keeping rank and sex constant.

In conclusion, this study did not meet the proposed objectives. The analysis of the merged data revealed duplicate records (mostly in M2 data set) or missing information (mostly in TRACES data base). This posed difficulty in performing an efficacious analysis and providing answers to study questions.

15. Publications and Presentations for this research study:
List all presentations **Authored by study staff** (Include lectures, abstracts, posters, etc), for the Entire study. **For RTOG and other national collaborations please include publications and presentations directly tied to the approved protocol only.**

Date	Authors	Title
NONE		

16. Signature of Principal/Associate Investigator:

MARIA R. KOHLER
Principal Investigator


Signature

26 May 2014
Date